5. 510(k) Summary

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Shavano Park, TX 78249+2095
210-375-8500

SUMMARY (21 CFR 807.92)

JUL 3 2012

Submitter's name: Vidacare Corporation
Address: 4350 Lockhill Selma Road
Shavano Park, TX 78249
Phone: 210-375-8500
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Name of contact person: Grace Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine CA 92606
Telephone: 949-262-0411
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Date the summary was prepared: May 21, 2012

Name of the device: The T.A.L.O.N.™ (Tactically Advanced Lifesaving IntraOsseous Needle) by Vidacare®

Trade or proprietary name: The T.A.L.O.N.™ (Tactically Advanced Lifesaving IntraOsseous Needle) by Vidacare®
Common or usual name: Intraosseous Infusion System
Classification panel: General Hospital

Product Code	Classification Regulation	Classification Name
FMI	880.5570	Needle, Hypodermic, Single Lumen

The legally marketed devices to which we are claiming equivalence [807.92(a) (3)]:

510(k) Number	*Trade or Proprietary or Model Name*	*Date of Concurrence*	*Manufacturer*
K063567	EZ-MIO Sternal	January 26, 2007	Vidacare Corp.
K970380	F.A.S.T.1 Intraosseous Infusion System	April 25, 1997	PYNG Medical Corp.

Description of the device:

The T.A.L.O.N.™ (Tactically Advanced Lifesaving IntraOsseous Needle) by Vidacare® has the same indications as the EZ-MIO Sternal, previously cleared by K063567. Both devices are for the purpose of obtaining vascular access during emergencies; both devices utilize a 15g 304 stainless steel manual needle set with a stylet and catheter that is manually inserted through the cortex of bone to the desired set depth within the medullary space to facilitate the infusion of medications and fluids.

Proposed Indications for Use:

Sternal IO Access is indicated for adult patients when rapid fluid or pharmacological resuscitation is required in emergencies.

Summary of the technological characteristics of our device compared to the predicate device:

The T.A.L.O.N. (Tactical Advanced Lifesaving IntraOsseous Needle) by Vidacare® and the Vidacare EZ-MIO Sternal predicate needle sets utilize the same needle set technology with a catheter of 15g stainless steel and stylet affixed to an ergonomically - designed manual driver/hub. Both needle sets are manually twisted through the cortical bone into a set depth within the same target area of the medullary space. Once inserted both devices function identically by allowing the user to remove the stylet by turning the stylet hub counter-clockwise leaving a catheter with a standard Luer-lock hub seated in the bone. The catheter's Luer-lock permits attachment of standard syringes and intravenous tubing for administration of medications and fluids.

The differences between the T.A.L.O.N. and EZ-MIO Sternal devices are intended for greater safety and ease of use. These differences include the deletion of the scalpel from the packaging and insertion step requiring scalpel; the addition of an adhesive backed "sternal locator" for correct anatomical placement, precise depth control with affixed depth setting probes and securing of device; and lengthening of the catheter from 25mm to 38.5mm to accommodate the collar of the sternal locator.

The predicate device, PYNG F.A.S.T. 1, K970380 has a similar indication for use, and relies on operator force to manually access the same anatomical location with a similar target patch (to Vidacare's sternal locator) for correct placement. The depth-setting probes of the Pyng F.A.S.T. 1 remain on the introducer and are removed after the steel-tipped infusion tubing is inserted through the cortical bone. The depth-setting probes of the T.A.L.O.N. device remain seated on the patient via the sternal locator to ensure stability of placement depth when the needle set is locked into the T.A.L.O.N. sternal locator hub.

Both predicates and the T.A.L.O.N. function identically once the needle sets are inserted into the medullary space and stylets are removed by permitting attachment of standard syringes and intravenous tubing for administration of medications and fluids.

All devices are sterile, single-use.

The Vidacare predicate and the T.A.L.O.N. (Tactical Advanced Lifesaving IntraOsseous Needle) by Vidacare® were compared in the following areas and found to have similar characteristics and/or to be substantially equivalent in the following areas:

Indication for Use
Anatomical sites
Biocompatibility
Needle Set design features
Component materials
Energy type (manual)
Environmental specifications
Ergonomics of the patient-user interface

Multiple post-clinical studies, bench testing and design validation tests were performed to evaluate the the T.A.L.O.N.™. The final study report is included with this submission with conclusions that the T.A.L.O.N.™ Intraosseous System Sternal Needle Set is safe and effective for gaining intraosseous vascular access through the sternum for the purpose of infusing fluids and medications. The data results and protocol have been provided both with the original submission and further detailed information has been provided with this addendum per the Agency's requests.

The bench testing for the T.A.L.O.N.™ device is included as the first phase of the Design Verification testing. The Design Verification testing for the T.A.L.O.N.™ device includes product performance testing consisting of dimensional and functional testing related to the use of the product. This testing confirms that the design inputs have been achieved for the product performance aspects of the product. A full analysis and summary of the testing results is included in the Functional Product Testing Report included in the body of the original submission and this addendum.

The combined studies, bench tests and design validation measures provided data supporting the safety and effectiveness of the T.A.L.O.N.™ Intraosseous System Sternal Needle Set for gaining intraosseous vascular access through the sternum for the purpose of infusing fluids and medications. The indications for the two predicates are identical to that of the T.A.L.O.N.™. All testing supported that both predicates and the T.A.L.O.N. function identically once the needle sets are inserted into the medullary space and stylets are

removed by permitting attachment of standard syringes and intravenous tubing for administration of medications and fluids which supports substantial equivalance for these devices. Thus showing that the T.A.L.O.N. and the predicates are Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 3 2012

Vidacare Corporation
Ms. Grace Holland
Regulatory Specialists, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K120661
Trade/Device Name: The T.A.L.O.N. ™ (Tactically Advanced Lifesaving IntraOsseous Needle) by Vidacare®
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 21, 2012
Received: May 23, 2012

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

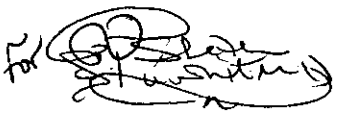
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Device Name: The T.A.L.O.N.™ (Tactically Advanced Lifesaving IntraOsseous Needle) by Vidacare®

Indications for Use:

Sternal IO Access is indicated for adult patients when rapid fluid or pharmacological resuscitation is required in emergencies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/2/12

)ivision Sign-Off)
vision of Anesthesiology, General Hospital
ifection Control, Dental Devices

510(k) Number: K120661